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44

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,446	08/16/2000	Fang Fang	014357/0278749	9403
53897	7590 08/23/2006		EXAMINER	
DUANE MORRIS LLP			LE, EMILY M	
101 WEST BROADWAY SUITE 900 SAN DIEGO, CA 92101-8285			ART UNIT	PAPER NUMBER
			1648	<del>-</del>
			DATE MAILED: 08/23/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/555,446	FANG, FANG				
Office Action Summary	Examiner	Art Unit				
	Emily Le	1648				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period was really reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICAT 36(a). In no event, however, may a reply to will apply and will expire SIX (6) MONTHS accuse the application to become ABAND	TION. be timely filed from the mailing date of this communication. ONED (35 U.S.C. § 133)				
Status						
1) Responsive to communication(s) filed on 11 Oc	ctober 2005 and 15 May 2006	<u>3</u> .				
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	· · · · · · · · · · · · · · · · · · ·					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11	, 453 O.G. 213.				
Disposition of Claims						
4) ⊠ Claim(s) 7-10,19,20,27,29,31,33 and 37-43 is/a 4a) Of the above claim(s) is/are withdrav 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ⊠ Claim(s) 7-10,19,20,27,29,31,33 and 37-43 are	vn from consideration.					
Application Papers						
9) ☐ The specification is objected to by the Examine	r.	•				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correcting 11) The oath or declaration is objected to by the Ex						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)         Paper No(s)/Mail Date     </li> </ol>	4) Interview Summ Paper No(s)/Ma 5) Notice of Inform 6) Other:					

Page 2

## **DETAILED ACTION**

## Reassignment Affecting Application Location

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

#### Status of Claims

2. Claims 1-6, 11-18, 21-26, 28, 30, 32 and 34-36 are canceled. Claims 7-10, 19-20, 27, 29, 31, 33 and 37-43 are pending.

### Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 7-10, 19-20, 37-38 and 43, drawn to a multivalent recombinant antibody against ICAM-1, and a topical formulation containing said multivalent recombinant antibody, wherein the topical formulation is directed to the prevention of rhinovirus infection.

Group II, claim(s) 27, 29 and 39-40, drawn to a method for preventing the common cold with the administration of the product of Group I.

Group III, claim(s) 31, 33 and 41-42, drawn to a method for preventing acute otitis media with the administration of the product of Group I.

4. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

Application/Control Number: 09/555,446

Art Unit: 1648

corresponding special technical features for the following reasons: The technical feature that is shared among the inventions is a multivalent recombinant antibody against ICAM-1. In the instant, this shared technical feature is not a special technical feature because it does not provide a contribution over the prior art, as evidenced by the combined teachings of Adair et al, Kipriyanov et al. and Pack et al. Adair et al. teaches a multivalent recombinant antibody against ICAM-1. While it is noted that the a multivalent recombinant antibody of Adair et al. may not have the same binding affinity to ICAM-1 as specified in the claims, however, Kipriyanov et al. teaches how to enhance binding affinity. Additionally, it is noted that the product of Group I further requires the multivalent recombinant antibody against ICAM-1 to have a coiled domain. This requirement can be satisfied with the teachings of Pack et al. Pack et al. teaches the attachment of a coiled domain to single chain antibody to polymerize the antibody, wherein it logically follows that polymerization of the molecules would result in an increased binding affinity.

Page 3

5. Additionally, the inventions of Groups II-III further lack unity with one another. In the instant, the special technical feature that defines the invention of Group II differs from the special technical feature that defines the invention of Group III. The special technical feature noted in the invention of Group II is the administration of a multivalent recombinant antibody that binds to ICAM-I to prevent the common cold. The special technical feature noted in the invention of Group III is the administration of a multivalent recombinant antibody that binds to ICAM-I to prevent acute otitis media. These special technical features differ from one another. Hence, the inventions listed as Groups II-III lack a corresponding special technical feature.

6. Should Applicant elects the invention listed as Group I, Application is further required to elect one species of the generic invention. The invention listed as Group I contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The claims are deemed to correspond to the species listed above in the following manner: Claim 43 recites the listed species.

Art Unit: 1648

- 9. The following claim(s) are generic: Claim 7 is the generic claim from which claim 43 recites a dependency.
- 10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. [In re Harnisch 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).] In the instant, the listed species lack unity with one another because a shared substantial structural feature contributing to the binding of ICAM-I cannot be ascertained among the listed species.
- 11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

Application/Control Number: 09/555,446 Page 6

Art Unit: 1648

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily Let \\ \/21/06 Patent Examiner Art Unit 1648